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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/928,007 | 08/10/2001 | Brian Eugene Baldwin | 50012-00004 | 6430 |

7590

04/08/2003

MARSH FISCHMANN & BREYFOGLE LLP
3151 S. Vaughn Way, Suite 411
Aurora, CO 80014

EXAMINER

NASH, BRIAN D

ART UNIT

PAPER NUMBER

3721

DATE MAILED: 04/08/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/928,007

Applicant(s)

BALDWIN ET AL.

Examiner

Brian D Nash

Art Unit

3721

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-32 is/are pending in the application.
- 4a) Of the above claim(s) 20-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3,5,6</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This action is in response to applicant's amendment received 21 January 2003. Examiner acknowledges: provisional election of claims 1-19 (Group I), amendment to claims 1, 9, 11, 20, and cancellation of claims 8 and 33-78.

Election/Restrictions

2. Applicant's election with traverse of claims 1-19 (Group I) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the process of claims 20-32 (Group II) cannot be utilized to make other and different products from the apparatus of claims 1-19 (Group I). This is not found persuasive because in the instant case, the apparatus as claimed can be used to practice another and materially different process such as one wherein a plurality of syringe bodies are already attached to a flexible belt.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 1, it is not clear what working structural relationship exists between the claimed elements so as to define an apparatus, i.e. a plurality of syringe bodies and belt attached to each does not clearly define a functioning apparatus as implied in the preamble.

In claim 15, it is not clear what is defined by "a second portion", i.e. it is not clear what the distinction is between the first and second portions of the belt.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-7 and 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,823,818 to Shaw. Shaw discloses the invention substantially as claimed including a plurality of cylindrical bodies attached via a flexible belt and having a predetermined orientation and spacing with at least one end of the cylindrical body accessible; the belt having opposing layers that can be adhesively joined and with the cylindrical body in between (see Shaw, Figs. 1,3). However, Shaw does not show syringe bodies attached to the flexible web.

It would have been an obvious matter of design choice to substitute a plurality of syringe bodies in place of the molded performs, since the applicant has not disclosed that the specific type of cylindrical body used solves any stated problem and it appears that the invention would perform equally well with the syringe bodies attached to the flexible web.

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7. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,823,818 to Shaw in view of US 5,884,457 to Ortiz et al. As discussed above in paragraph 6 of this office action, Shaw discloses the invention substantially as claimed, but does not specifically disclose syringe bodies wherein the syringes have a removable cap and fluid port with outer flange on the dispensing end and a slidably disposed plunger on the opposing end (see Ortiz, Figs. 2-4). However, Ortiz teaches an apparatus using a plurality of syringes wherein the syringes have a removable cap and fluid port with outer flange on the dispensing end and a slidably disposed plunger on the opposing end for the purpose of producing a plurality of prefilled syringes with removable caps.

In view of Ortiz, it would have been obvious to one having ordinary skill in the art to have used the syringe bodies having a removable cap and fluid port with outer flange on the dispensing end and a slidably disposed plunger on the opposing end in place of the molding preforms for the purpose of producing a plurality of prefilled syringe bodies.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Takumi, Tschepke et al, Keusch et al, Raghavachari et al, and Senelonge are cited to show related references.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Nash whose telephone number is (703) 305-4959. The examiner can normally be reached on Monday – Thursday from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached at (703) 308-2187.

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The fax numbers for this Group are:

Before Final 703-872-9302

After Final 703-872-9303

Customer Service 703-872-9301

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1148.

Brian D. Nash
27 March 2003

A handwritten signature in black ink, appearing to read 'Rinaldi I. Rada', with a long horizontal flourish extending to the right.

Rinaldi I. Rada
Supervisory Patent Examiner
Group 3700